DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION, Federal Y2K Biomedical Equipment Clearinghouse
Compliant Products – FORM FDA 3474

Form approved: OMB No. 0910-0397
Expiration Date: February 29, 2000
See OMB Statement on reverse

Report all compliant products using this form or a photocopy of it, and return as indicated in the enclosed **Options for Reporting** page. For detailed instructions, please refer to the appropriate line number on the **BACK** of this form.

Line #	Manufacturer Information	
1.	Manufacturer Name	
2.	Division *(see instructions on the back of this form)*	
3.	Enter Your FDA Assigned Owner/Operator Number	
	Compliant Product Information	
		COMPLIANT PRODUCT A
4a.	Is this product FDA regulated?	❑ **YES** ❑ **NO**
5a.	FDA Classification Number *(see instructions on the back of this form)*	8 ☐☐.☐☐☐☐ **FOR DETAILS AND INSTRUCTIONS SEE THE ENCLOSED LIST OF PRODUCT CLASSIFICATION NAMES.**
	Generic Description *(e.g., mass spectrometer)* *Only for non-FDA-classified or scientific research equipment.*	*(For a product that has not been classified by the FDA or is scientific research equipment, please provide a generic description in the block below.)*
6a.	Trade or Brand Name	
7a.	Model Number(s)	
8a.	Original Manufacturer *(Name of the manufacturer under which this product was originally marketed.)*	
9a.	Serial Number(s)	
10a.	Software Version Number(s)	
		COMPLIANT PRODUCT B
4b.	Is this product FDA Regulated?	❑ **YES** ❑ **NO**
5b.	FDA Classification Number *(see instructions on the back of this form)*	8 ☐☐.☐☐☐☐ **FOR DETAILS AND INSTRUCTIONS SEE THE ENCLOSED LIST OF PRODUCT CLASSIFICATION NAMES.**
	Generic Description *(e.g., mass spectrometer)* *Only for non-FDA-classified or scientific research equipment.*	*(For a product that has not been classified by the FDA or is scientific research equipment, please provide a generic description in the block below.)*
6b.	Trade or Brand Name	
7b.	Model Number(s)	
8b.	Original Manufacturer *(Name of the manufacturer under which this product was originally marketed.)*	
9b.	Serial Number(s)	
10b.	Software Version Number(s)	

DUPLICATE THIS FORM AS NECESSARY

Federal Y2K Biomedical Equipment Clearinghouse
Instructions – FORM FDA 3474

This form is used to report compliant product information. Please report all compliant products on this form and return as indicated in the enclosed **Options for Reporting** page.

If you have questions about completing this form or the Federal Y2K Biomedical Equipment Clearinghouse please call toll free 1-877-744-1522 between 8:30am and 5:00pm Monday through Friday Eastern Time, or Email the Y2K Clearinghouse at y2kstatus@bah.com. You may also fax your completed forms to 1-301-881-1848.

Line Number Key

Manufacturer Information	
1. Manufacturer Name	Name of the Manufacturer submitting the product information.
2. Division	Name of the Division, if this report is for ONE specific division. Complete ONE form for each division that manufactures biomedical equipment. Please leave blank if you are reporting for the entire company.
3. Enter Your FDA Assigned Owner/Operator Number	If the Manufacturer submitting Y2K status information is FDA regulated, please enter your FDA assigned Owner/Operator Number.
Compliant Product Information	***(The following applies to Compliant Product Sections A and B)***
4. Is this product FDA regulated?	Is this product FDA regulated?
5. Classification Number	Use the device classification as identified in the Device Classification Regulation of 21 CFR 860-892 (enclosed). For a product that has not been classified by the FDA or is scientific research equipment, please provide a generic description in the block provided (e.g., mass spectrometer).
6. Trade or Brand Name	Commonly used name that identifies the product (i.e., the name that appears on the product label).
7. Model Number(s)	Model number or range of numbers associated with the product that uniquely identifies it.
8. Original Manufacturer	Identify the name of the manufacturer under which this product was originally manufactured, if it is different than Line #1.
9. Serial Number(s)	Serial number or range of numbers for the compliant product, if applicable. Use "All" to indicate all serial numbers associated with the compliant product.
10. Software Version Number(s)	Software version or range of numbers for the compliant product, if applicable. Use "All" to indicate all software version numbers associated with the compliant product.

Public reporting burden for this collection of information is estimated to average 11.5 hours per response, including the time for reviewing instructions, search existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Year 2000 Coordinator (HFZ-Y2K)
Center for Devices and Radiological Health, FDA
9200 Corporate Boulevard
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

YEAR 2000 READINESS DISCLOSURE

Instructions – FORM FDA 3474 (9/99)